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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,595	09/23/2002	Sunil Ahuja	4003.001600	2489
20792 7590 10/19/2007 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			EXAMINER SITTON, JEHANNE SOUAYA	
			ART UNIT 1634	PAPER NUMBER
			MAIL DATE 10/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/089,595	Applicant(s) AHUJA ET AL.	
	Examiner Jehanne S. Sitton	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56, 57, 63-66, 70, 94, 95 and 114-118 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 56, 57, 63-66, 70 is/are allowed.
- 6) ☒ Claim(s) 94, 95 and 114-118 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/19/2007 has been entered.
2. Currently, claims 56-57, 63-66, 70, 94-95, and newly added claims 114-118 are pending in the instant application and under consideration at this time. The following rejections are either reiterated or newly applied. They constitute the complete set being presently applied to the instant Application. This action is Non-FINAL.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Applicant's arguments at pages 8 and 9 of the response dated 6/19/2007 are persuasive. Accordingly, the rejection of claims 57 and 65 under 35 USC 102(e) as being anticipated by Kaslow is withdrawn. All other rejections not reiterated herein are moot in view of either the amendments to the claims or the cancellation of the claims.

Claim Rejections - 35 USC § 112

5. Claims 94-95, and 114-118 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claims 94, 95, and 114 are indefinite in their recitation of “genotyping the subject for the presence of a CCR5 haplotype pair”. It is unclear if the claims are limited to the actual detection of the haplotype pair (in which case, they would be identical in scope to claims 56, 57, and 70), or if they more broadly encompass genotyping any position of the CCR5 haplotype as long as it determines whether the haplotype is present or not, but do not actually require that the haplotype be detected. The metes and bounds of the claims are different in each of these alternative embodiments. Although the specification teaches how to perform a genotyping step, the claim does not make clear if the recitation limits the claim to the detection of a haplotype pair or to a screen to determine the alleles of a particular haplotype.

Claim Rejections - 35 USC § 102

6. Claims 94, 95 and newly added 114-118 are rejected under 35 U.S.C. 102(b) as being anticipated by Mummidi (Mummidi et al; Nature Medicine, vol. 4, July 1998, pages 786-793).

Claims 94, 95, and 114-18 are drawn to “genotyping for the presence of a CCR5 haplotype pair”. The only active step is “genotyping for” which does not make clear if the claims are limited to the actual detection of the haplotype pair, if they encompass genotyping to determine the identity of the allele at each position of the CCR5 haplotype to determine if the particular haplotype is present, or if they more broadly encompass genotyping any position of the

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CCR5 haplotype as long as it determines whether the haplotype is present or not, but do not require that the haplotype be detected. Accordingly, the claims have been given their broadest reasonable interpretation to be drawn to a method of determining whether a particular haplotype is there or not. Mummidì teaches methods of genotyping to determine alleles of CCR5 haplotypes (see table 1). Further, at table 2, Mummidì teaches detection of the CCR5 $\Delta 32$ allele (deletion) in Caucasians. The specification at page 136 (lines 21-29) and figure 1D, define the 9 different CCR5 haplotypes (HHA, HHB, HHC, HHD, HHE, HHF*1, HHF*2, HHG*1, and HHG*2). The HHE haplotype is defined as including the CCR5 wt (or "+") allele (lack of 32 base pair deletion). Accordingly, Mummidì inherently teaches detecting the lack of a HHE/HHE haplotype pair in human Caucasians because the HHE haplotype requires the CCR5 wt allele (lack of $\Delta 32$). Additionally, at table 2, Mummidì teaches detection of the CCR2 64I allele in Caucasians and African Americans. The specification at page 136, teaches that the only haplotype to contain the 64I variant is HHF*2. Accordingly, in teaching detection of the CCR2 64I variant, Mummidì inherently teaches detecting the absence of HHE/HHE, HHC/HHF*1, HHC/HHE, HHC/HHC, HHC/HHD in Caucasians and African Americans because each of these haplotypes require the CCR2 64V variant.

Alternatively, the claims can be interpreted as requiring genotyping each allele of the CCR5 haplotypes as defined by the instant specification (that is, positions 29, 208, 303, 627, 630, 676, 927, $\Delta 32$, and the CCR2 V/I allele), to determine the identity of the allele, but that detection of a particular haplotype or haplotype pair is not required.

Mummidì teaches genotyping positions of the CCR5 gene of individuals on both CCR5 alleles, including detecting the CCR2 V/I mutation and the 32 base pair deletion in the CCR5

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ORF (see Figure 1) using a set of nucleic acids (page 792, col. 2 “Genotype analysis” to page 793 para 1 first column). Further, Mummidi teaches sequencing the CCR5 region from -731 to +981 (para bridging pages 792-793). Thus Mummidi teaches “genotyping”, that is determining the identity of the allele, at each position of the claimed CCR5 haplotypes at each position as defined by the specification (that is, positions 29, 208, 303, 627, 630, 676, 927, Δ 32, and the CCR2 V/I allele).

It is noted that the preamble recitation has not been given any patentable weight as the genotyping step does not require the actual detection of the indicated CCR5 haplotype pairs.

7. Claims 94, 95, and 114-118 are rejected under 35 U.S.C. 102(e) as being anticipated by Kaslow (US Patent, 6,372,435).

With regard to claims 94, 95, 114-118, which are drawn to “genotyping for the presence of a CCR5 haplotype pair”, detecting the “absence” of particular haplotype pairs. The only active step is “genotyping for” which does not make clear if the claims are limited to the actual detection of the haplotype pair, if they encompass genotyping to determine the identity of the allele at each position of the CCR5 haplotype to determine if the particular haplotype is present, but do not actually require that the haplotype be detected, or if they more broadly encompass genotyping any position of the CCR5 haplotype as long as it determines whether the haplotype is present or not, but do not require that the haplotype be detected. Accordingly, the claims have been given their broadest reasonable interpretation to be drawn to a method of determining whether a particular haplotype is there or not. At table 5, Kaslow teaches detection of the CCR5 Δ 32 allele (deletion) in Caucasians (annotation b). The specification at page 136 (lines 21-29)

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and figure 1D, define the 9 different CCR5 haplotypes (HHA, HHB, HHC, HHD, HHE, HHF*1, HHF*2, HHG*1, and HHG*2). The HHE haplotype is defined as including the CCR5 wt (or “+”) allele (lack of 32 base pair deletion). Accordingly, Kaslow inherently teaches detecting the lack of a HHE/HHE haplotype pair in humans as well as human Caucasians because the HHE haplotype requires the CCR5 wt allele (lack of $\Delta 32$). Additionally, at table 8, Kaslow teaches detection of the CCR2 64I allele in Caucasians and African Americans. The specification at page 136, teaches that the only haplotype to contain the 64I variant is HHF*2. Accordingly, in teaching detection of the CCR2 64I variant, Kaslow inherently teaches detecting the absence of HHE/HHE, HHC/HHF*1, HHC/HHE, HHC/HHC, HHC/HHD, in Caucasians and African Americans because each of these haplotypes require the CCR2 64V variant. Further, Kaslow teaches that the haplotype pair HHC/HHD (P*0101/*0103) was not found (col. 28, lines 51-52 and table 4). It is noted that the preamble recitation has not been given any patentable weight as the genotyping step does not require the actual detection of the indicated CCR5 haplotype pairs.

The specific haplotype pairs HHE/HHE, HHC/HHF*1, HHC/HHE, and HHC/HHD are not taught by Kaslow as the genotype assessments made by Kaslow do not distinguish HHE from HHG*1 from HHG*2 (P*0201), or HHF*1 from HHF*2 (P*0202).

Conclusion

8. Claims 56, 57, 63-66 and 70 are allowable over the cited prior art.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-

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0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Jehanne Sitton/
Primary Examiner
Art Unit 1634
10/12/2007